Patent /Docket No. 23100.40
Customer No. 27683

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:
McANALLEY, B.

Serial No.: 10/001,439

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For: DIETARY SUPPLEMENT COMPOSITIONS

Group Art Unit: 1654

Examiner: Coe, Susan D.

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BRIEF ON APPEAL

Commissioner of Patents and Trademarks
Washington, D.C. 20231

This Brief is submitted in connection with an appeal from the final rejection of the Examiner dated August 12, 2002, finally rejecting claims 1, 8-17, 19-20 and 24, all of the pending claims in this application. Two additional copies of this Brief are also submitted.

REAL PARTY IN INTEREST

The real party in interest is Mannatech, Inc. a Texas corporation, with its principal office at 600 South Royal Lane, Suite 200, Coppell, Texas 75019.

RELATED APPEALS AND INTERFERENCES

There are no related appeals and no related interferences regarding the above-identified patent application.

STATUS OF CLAIMS

Original claims 1, 8-17, 19-20 and 24 are pending, stand finally rejected and are on appeal here. Claims 1, 8-17, 19-20 and 24 are attached as Appendix A.

STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendments have been filed after Final Rejection and the claims as set out in the Appendix include all entered amendments.

SUMMARY OF THE INVENTION

Embodiments of the present invention relate to dietary supplement compositions comprising a combination of colostrum, lactoferrin and β-glucan, thus providing an improvement over previous compositions which lacked one or more of these components. When absorbed in combination the effects of colostrum, lactoferrin and β-glucan on the health and well-being of the recipient are surprisingly beneficial, including: promotion of immune system health, promotion of body health and athletic performance, promotion of gastrointestinal (GI) tract health, promotion of blood vessel health, promotion of glucose utilization and blood sugar balance, improved pathogen resistance, improved cancer inhibition and improved mental function and toxin-related activities. Absorption of the components of the compositions in the oral cavity, rather than through the lining of either the stomach or intestine is particularly efficacious, therefore the present invention includes the provision of the components of the inventive composition in a mucosal delivery format as a chewable product.

ISSUE

Whether claims 1, 8-17, 19-20 and 24 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as "Donzis '015"), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as "Paul '989") and International Publication No. WO 97/05884 to Plaut (hereafter referred to as "Plaut '884").

GROUPING OF CLAIMS

As to the rejection of claims 1, 8-17, 19-20 and 24, directed to a dietary supplement composition for a mammal, comprising a nutritionally effective amount of β-glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides, it is Applicants' intention that solely for the purposes of this appeal, the rejected claims stand or fall together.

ARGUMENT

The Examiner uses Donzis '015 to teach that beta-glucan strengthens the immune system. (page 5, Paper 6). Paul '989 is used to teach that a composition containing pectin, lactoferrin, and saccharides strengthen the immune system. *id.* Plaut 884 is used by the Examiner to teach that lactoferrin and colostrum strengthen the immune system. *id.* The Examiner has taken the position that "there is motivation known in the art to combine substances together that are all known to have the same pharmaceutical effect. The references all teach that the claimed ingredients are used in compositions that strengthen the immune system. . . Therefore, it would have been obvious to combine the compositions taught by the prior art into one composition." (page 2, Paper 12). The Examiner has also argued that "it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." *id.*

The Applicant believes the Examiner has applied an outdated and incorrect standard to support the rejection. It is submitted that the Examiner has not factually support a prima facie case of obviousness based on the Donzis '015, Paul '989 and Plaut '884 references for the following reasons:

Donzis '015 discloses the use of beta (1,3) yeast extract glucan particles as nutritional supplements. Contrary to the claimed subject matter, however, Donzis '015 does not disclose or suggest a composition which includes beta (1,3) yeast extract glucan and a complex of essential saccharides.

Paul '989 discloses an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health. Paul '989 discloses that the fiber portion of the dietary supplement may include pectin and fructo-

oligosaccharides. Paul '989 also discloses that the dietary supplement may include lactoferrin as an inhibitor of detrimental iron-catalyzed processes. Contrary to the claimed subject matter, however, Paul '989 does not disclose or suggest a composition which includes a complex of essential saccharides.

Plaut '884 discloses an infant formula which includes pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease and an IgA protease precursor. Contrary to the claimed subject matter, however, Plaut '884 does not disclose or suggest a composition which includes a complex of essential saccharides.

Accordingly, none of Donzis '015, Paul '989 or Plaut '884 taken alone disclose or suggest the subject matter of any of claims 1, 8-17, 19-20 and 24.

It is respectfully submitted that the combination of Donzis '015, Paul '989 and Plaut '884 is improper. According to MPEP § 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Since the Federal Circuit first addressed this issue in *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984), the Federal Circuit has consistently held that:

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ***Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.***
>
> *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)); *In re Fritch*, 23 USPQ 2d 1780, 1783-1784 (Fed. Cir. 1992).

Also, the case law is clear that there must be evidence that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. It is also clear that a rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, *with no knowledge of the claimed invention*, would have selected these components for combination in the manner claimed. *Ecolochem Inc. v. Southern California Edison,* 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). Here, no such evidence has been presented. In addition, there is absolutely no teaching, suggestion or motivation to support the combination of Donzis '015, Paul '989 and Plaut '884.

The current case law makes it clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See *In re Dembiczak*, 50 USPQ2d, 1614, 1617 (Fed. Cir. 1999). "Combining prior art references without ***evidence*** of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight." *Id.* It is respectfully submitted that the only way Donzis '015, Paul '989 and Plaut '884 could be pieced together to defeat patentability is indeed to use Applicant's disclosure as a blueprint. Therefore, the combination of references is improper.

To justify the rejection, however, the Examiner cites *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The Applicant notes that the latest of these cases was decided over thirty years ago – long before the existence of the Federal Circuit.

As the Federal Circuit has recognized, "***standards for the patenting of chemical entities have evolved***." *In re Mayne*, 41 USPQ 2d 1451, 1453-54 (Fed. Cir. 1997) (emphasis added). When relying on numerous references or a modification of prior art, "***it is incumbent upon the examiner to identify*** some suggestion to combine

references or make the modification." *id.* Thus, it is respectfully submitted that the thirty year old cases cited by the Examiner no longer reflect the Federal Circuit's current standard for obviousness.

Arguably, the thirty year old cases cited by the Examiner simply restate the "obvious to try" test. In other words, if the two ingredients are useful for the same purpose, then it is obvious to try to combine the ingredients. However, this is not the current standard for obviousness. As the Federal Circuit has stated:

> At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, ***this is not the standard of 35 U.S.C. §103***.
>
> *In re Geiger*, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987)(emphasis added).

The current standard for obviousness is stated below:

> Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the tempting but forbidden zone of hindsight, . . . when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field. . . . Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. . . . In this case, the Board fell into the hindsight trap. . . . The range of sources available, however, ***does not diminish the requirement for actual evidence***. ***That is, the showing must be clear and particular.***
>
> *In re Dembiczak*, 50 USPQ 2d 1614, 1616-17 (Fed. Cir. 1999) (quotations omitted)

It is respectfully submitted that there is no evidence presented by the Examiner for the motivation which would lead one skilled in the art to combine the references.

Making an assertion that "there is motivation known in the art to combine substances together that are all known in the art to have the same pharmaceutical effect" is not the clear and particular "evidence" demanded by the Federal Circuit under the current standard. Thus, under the current standard set by the Federal Circuit, the Examiner has not made a prima facie case for obviousness.

The Examiner admits the use of hindsight, but justifies this impermissible use by arguing that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." In support of this incorrect assertion, the Examiner cites *In re McLaughlin,* 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) - another thirty year old case. The Applicant respectfully disagrees and argues that under the current standards, the Federal Circuit has forbidden any use of hindsight, as stated below:

> This court ***forbids the use of hindsight*** in the selection of references that comprise the case of obviousness.

In re Rouffet, 47 USPQ 2d 1453, 1458 (Fed. Cir. 1998)(emphasis added).

Thus, it is respectfully submitted that the Examiner has used an outdated and impermissible standard to justify the use of hindsight.

There are hundreds of ingredients that strengthen the immune system. To argue that the claimed combination is obvious in light of the hundreds of possible ingredients is impermissible hindsight. Without the benefit of such hindsight, as the Examiner has essentially admitted, the Examiner cannot maintain that the combination as claimed is obvious in light of the of the prior art. It is respectfully submitted that the only way Donzis '015, Paul '989 or Plaut '884 could be pieced together to defeat patentability is indeed to use Applicant's disclosure as a blueprint.

Accordingly, for the foregoing reasons, it is respectfully submitted that none of Donzis '015, Paul '989 and Plaut '884 disclose or suggest the subject matter of claims 1, 8-17, 19-20 and 24. Moreover, it is respectfully submitted that it is improper to combine any of such references because there is no motivation or suggestion for such combination to achieve the applicant's claimed dietary supplement, and even if there were, the result would not be the dietary supplement of claims 1, 8-17, 19-20 and 24.

For all of the foregoing reasons, it is respectfully submitted that claims 1, 8-17, 19-20 and 24 be allowed. A prompt notice to that effect is earnestly solicited.

Respectfully submitted,

Date: June 18, 2003

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APPENDIX

1. A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β-glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.

8. The dietary supplement composition of claim 1 wherein said mammal is a human.

9. The dietary supplement composition of claim 1 wherein said composition comprises from about 5 to about 83.3 weight percent of said colostrum, from about 0.909 to about 6.67 weight percent of said lactoferrin, from about 0.1 to about 1.25 weight percent of said citrus pectin, and from about 0.001 to about 10 weight percent of said β-glucan.

10. The dietary supplement composition of claim 4 further comprising a nutritionally effective amount of citric acid.

11. The dietary supplement composition of claim 10, wherein said composition comprises from about 0.25 to about 2.4 weight percent of said citric acid.

12. The dietary supplement composition of claim 1 further comprising a nutritionally effective amount of citric acid, dextrose, magnesium stearate, silicon dioxide and stearic acid.

13. The dietary supplement composition of claim 12, wherein said composition comprises from about 0.25 to about 2.4 weight percent of said citric acid, from about 35.8 to about 88.3 weight percent of said dextrose, from about 0.25 to about 1.5 weight percent of said magnesium stearate, from about 0.25 to about 1.5 weight percent of said silicon dioxide, and about 1.67 to about 2.5 weight percent of said stearic acid.

14. The dietary supplement composition of claim 12, further comprising one or more of a nutritionally acceptable carrier, diluent or flavoring.

15. The dietary supplement composition of claim 13, further comprising a flavoring in an amount of about 0.15 to about 1.31 weight percent.

16. The dietary supplement composition of claim 1 wherein said composition is prepared in a chewable delivery system.

17. The dietary supplement composition of claim 14 wherein said composition comprises about 9.63 weight percent of said colostrum, about 0.642 weight percent of said lactoferrin, about 0.321 weight percent of said citrus pectin, about 1.28 weight percent of said β-glucan, about 0.626 weight percent of said citric acid, about 83.3 weight percent of said dextrose, about 0.482 weight percent of said magnesium stearate, about 0.482 weight percent of said silicon dioxide, about 1.93 weight percent of said stearic acid, and about 1.31 weight percent of said nutritionally acceptable carrier, diluent, or flavoring.

19. The dietary supplement composition of claim 1, wherein the complex of essential saccharides comprises saccharides provided in oligomeric or polymeric forms as found in: gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

20. A dietary supplement composition for producing in a mammal a first effect selected from the group consisting of regulation of the immune system, regulation of cytokine release, prevention of autoimmune response from intestinal pathogens, promotion of phagocytosis by neutrophils, stimulation of B cell and antibody secretion,

inhibition of mast cell enzyme involved in allergic airway response, enhancement of natural killer cell activity, stimulation of muscle protein synthesis, inhibition of muscle protein breakdown, stimulation of wound healing, stimulation of tissue repair, induction of cartilage formation and bone repair, anti-inflammatory effects, enhancement of hematopoietic activity, increase in insulin-like growth factor in tissues, antidiarrheal effect on gastrointestinal tract infection, stimulation of gastrointestinal tract growth, improvement in function of the gastrointestinal tract, promotion of the growth of beneficial gastrointestinal bacteria, lowering blood cholesterol, improving glucose tolerance, reducing average blood glucose in non-insulin-dependent diabetics, stimulation of glucose uptake by muscles, inhibition of the binding of bacteria to a host tissue, inhibition of the growth of bacteria, protection against viruses, enhancing activity of antibiotics, antifungal effects, anti-amoebic effects, prevention of tumor development, inhibition of tumor cell growth, inhibition of tumor metastasis, enhancement of natural killer cell toxicity to tumors, improvement in Alzheimer's dementia, antioxidant effects, and reaction against bacterial toxins, said dietary supplement composition comprising a nutritionally effective amount of β-glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.

24. The dietary supplement composition of claim 20, said dietary supplement composition producing in a mammal a second effect selected from the group consisting of enhancing bile acid excretion, enhancing cholesterol excretion, reducing artherosclerosis, binding heavy metals, stimulation of immune function, resistance to infection, suppression of infection, increase of tissue repair and healing, promotion of body health and athletic performance, promotion of gastrointestinal tract health, promotion of blood vessel health, promotion of glucose utilization and blood sugar balance, improved cancer inhibition and improved mental function.